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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,308	01/10/2001	Howard A. Fields	14114.0349U2	9952
23859	7590	04/07/2005	EXAMINER	
NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/758,308

Applicant(s)

FIELDS ET AL

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-25 and 32-44 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 4-6, 11-16, 18-23 and 32-39 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 17 is/are allowed.
- 6) ☒ Claim(s) 9, 10, 24, 25, 40, 41, and 43-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The response to the previous office action filed on 01/04/2005 has been acknowledged. Claims 7-8, 26-31 have been canceled. New claims 43 and 44 are added. Claims 1-6, 9-25, 32-44 are pending. Claims 1-2, 4-6, 11-16, 18-23 and 32-39 are withdrawn from the consideration. Claims 3, 9, 10, 17, 24, 25, 40, 41 and 43-44 are considered by the examiner.

Upon considering all pending claims, a new ground rejection is made on the record.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10, 41, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Hijikata M et al. (Proc. Natl. Acad. Sci. USA 1993 Vol. 90, pp. 10773-10777).

3. Hijikata et al. teach a fusion protein encoded by nucleic acid sequence from 729 to 3010 or 729-2052, which comprises a 100% identical fragment of the claimed HCV NS3 protein from residue 1471 to 1573 (SEQ ID NO: 2) fused with Dihydrofolate Reductase (DHFR) gene of Escherichia Coli (See section of MATERIALS AND METHODS on pages 10773-10774, and Fig. 1 & Fig. 2), but it is not the HCV full length polyprotein. The mosaic polypeptide is described in the specification as an artificial proteins constructed from diagnostically relevant antigenic regions derived from different HCV proteins, preferably, as a mosaic polypeptides containing antigenic epitopes from the core protein, NS3 protein, and NS4 protein or optionally containing an additional antigenic epitope from either the NS4 protein or the NS5a protein or both. Moreover, the rejected claims do not exclude that the claimed mosaic polypeptides contain other amino acid residues encoding other epitopes of other HCV antigenic protein(s) in view of the definition of mosaic polypeptide in the specification since they all use open language “comprising” to describe the claimed mosaic polypeptide. To this context, the fusion protein disclosed by Hijikata et al. is a mosaic polypeptides because it does not only comprises the HCV NS3 protein p70, but also NS5 (See Results on page 10774 and Figs 2-3), inherently, it

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comprises not only NS3 epitopes, but also NS5 epitopes. Hijika et al. also disclose a method of using anti-HCV NS3 antibody (anti-p70 antibody or  $\alpha$ -p70) to detect the said HCV fusion protein, in particular, the HCV NS3 encoded p70 protein (See page 10775, 2<sup>nd</sup> column). Because the HCV NS3 and NS5 are all immunogenic, the product comprising them is considered as immunogenic composition since the composition comprising the HCV NS3 and NS5 inherently comprises immunogenic characteristic. Moreover, because the fusion protein comprises other non-HCV protein, it is not considered as a native HCV polyprotein. Therefore, the claims are anticipated by the cited reference.

4. Claims 9, 24, 40, 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Takemura et al. (EP005160A1).

5. Takemura et al. teach a fusion protein comprising HCV core polypeptide 120 (120NA) or 156 (150NA) fused with a nucleic acid binding motif encoded by 110 bp DNA sequence (Examples, 1-4 on pages 6-7). The 120NA was also prepared by fusing to 10 lysin residues (DE3)/pW6AHCV core K10 (Reference example 3 on page 7). Furthermore, the fusion protein is disclosed to contain two 120NA HCV core polypeptides, which is further fused with 47kD antigen derived from TP (*Treponema pallidum*) to yield TP47C2NA. The composition comprising each of the fusion proteins as described above is also disclosed (See examples 3, reference examples 2, 3, 6-16). Takemura et al. also teach that all antigens described above can be recognized by the anti-HCV antibodies positive serum, indicating all of the antigens described above are immunogenic. Therefore, the claims are anticipated by the cited reference.

6. Claims 9, 40, 44 are rejected under 35 U.S.C. 102(b) as being anticipated by SRLS (JP07322881-A).

7. JP07322881-A teaches a fusion protein with 1010 amino acid residues that comprises 1-91 amino acid residues of HCV core polypeptide (See pages 8-9). Because the definition of mosaic polypeptides in the specification is directed to an artificial composite protein constructed from diagnostically relevant antigenic regions derived from different HCV proteins, which is preferably, the mosaic polypeptides containing antigenic epitopes from the core protein, NS3 protein, and NS4 protein or preferably, optionally containing an additional antigenic epitope

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from either the NS4 protein or the NS5a protein or both. Moreover, considering the rejected claims that use an open language "comprising" to describe the mosaic polypeptide, the claims leave open in that the claimed mosaic polypeptide does not limit to contain a core protein with amino acid residue 1 to 91 amino acid residues only, it may comprise other amino acid residues beyond the core protein that encodes other epitopes by other HCV antigenic protein(s). To this context, the fusion protein disclosed by JP07322881-A is a mosaic polypeptide, which is used for diagnosis of HCV infection. Hence, the reference of JP07322881-A anticipates the rejected claims.

### *Conclusion*

Claims 3, 17 and 43 are free of art rejection. However, the application would not be allowed until applicant cancel the non-allowable claims.

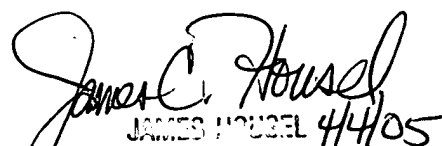
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

03/23/2005

  
JAMES HOUSEL 4/4/05  
SUPERVISOR, PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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